

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 07 FEB 2006

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Applicant's or agent's file reference 666985C:MOB:RMC	<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. <b>PCT/AU2005/000142</b>	International filing date ( <i>day/month/year</i> ) 4 February 2005	Priority date ( <i>day/month/year</i> ) 6 February 2004	
International Patent Classification (IPC) or national classification and IPC			
Int. Cl.			
<b>A61K 31/166</b> (2006.01)		<b>A61P 1/00</b> (2006.01)	
<b>A61K 31/606</b> (2006.01)		<b>A61P 1/06</b> (2006.01)	
		<b>A61P 1/12</b> (2006.01)	
		<b>A61P 1/14</b> (2006.01)	
Applicant BORODY, Thomas Julius et al			

- This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 3 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, comprising:
  - ☐ (*sent to the applicant and to the International Bureau*) a total of sheets, as follows:
    - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
    - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
  - ☐ (*sent to the International Bureau only*) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

- This report contains indications relating to the following items:

- |   |   |
|---|---|
| <input checked="" type="checkbox"/> Box No. I | Basis of the report   |
| <input type="checkbox"/> Box No. II           | Priority  |
| <input type="checkbox"/> Box No. III          | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/> Box No. IV           | Lack of unity of invention  |
| <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI           | Certain documents cited   |
| <input type="checkbox"/> Box No. VII          | Certain defects in the international application  |
| <input type="checkbox"/> Box No. VIII         | Certain observations on the international application   |

Date of submission of the demand 6 September 2005	Date of completion of this report 11 January 2006
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  <b>Michael Grieve</b> Telephone No. (02) 6283 2267

**Box No. I Basis of the report**1. With regard to the **language**, this report is based on:☒ The international application in the language in which it was filed☐ A translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of:☐ international search (under Rules 12.3(a) and 23.1 (b))☐ publication of the international application (under Rule 12.4(a))☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:☒ the international application as originally filed/furnished☐ the description:

pages as originally filed/furnished

pages\* received by this Authority on \_\_\_\_\_ with the letter of

pages\* received by this Authority on \_\_\_\_\_ with the letter of

☐ the claims:

pages as originally filed/furnished

pages\* as amended (together with any statement) under Article 19

pages\* received by this Authority on \_\_\_\_\_ with the letter of

pages\* received by this Authority on \_\_\_\_\_ with the letter of

☐ the drawings:

pages as originally filed/furnished

pages\* received by this Authority on \_\_\_\_\_ with the letter of

pages\* received by this Authority on \_\_\_\_\_ with the letter of

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.3. ☐ The amendments have resulted in the cancellation of:☐ the description, pages☐ the claims, Nos.☐ the drawings, sheets/figs☐ the sequence listing (*specify*):☐ any table(s) related to the sequence listing (*specify*):4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).☐ the description, pages☐ the claims, Nos.☐ the drawings, sheets/figs☐ the sequence listing (*specify*):☐ any table(s) related to the sequence listing (*specify*):

\* If item 4 applies, some or all of those sheets may be marked "superseded."

**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims 1 to 13	YES
	Claims	NO
Inventive step (IS)	Claims 1 to 13	YES
	Claims	NO
Industrial applicability (IA)	Claims 1 to 13	YES
	Claims	NO

**2. Citations and explanations (Rule 70.7)**

D1: AU-A-87301/91

D2: WO 1992/016206A

D3: WO 1992/016214A

D4: Drugs &amp; Aging Vol.19 No.5 (2002) pages 355-363

D5: Alimentary Pharmacology &amp; Therapeutics Vol.6 No.1 (1992) pages 51-59

D6: Drug Safety Vol.23 No.5 (2000) pages 429-448

**NOVELTY (N)**

Claims 1 to 13 are considered to meet the criteria set out in PCT Article 33(2) as possessing novelty over the disclosure of documents D1 to D3. It is noted that document D1 discloses the use of salicylic acid derivatives (of which balsalazide is a known example) in the treatment of non-inflammatory and non-infectious bowel disorders such as irritable bowel syndrome, constipation, non-ulcer dyspepsia, and diverticular disease. Similarly, documents D2 and D3 disclose the use of 5-ASA compounds (of which balsalazide is, again, a known example) in the treatment of irritable bowel syndrome – diarrheal phase or Type (IBS-D). These documents, however, neither disclose nor suggest that balsalazide is unexpectedly far more powerful in treating the above-mentioned bowel disorders when compared to other 5-ASA compounds such as mesalazine.

As a result, the matter of the present Claims 1 to 13 is considered to be novel.

Documents D4 to D6 are merely considered to define the general state of the art, in that balsalazide is known to be effective in the treatment of irritable bowel disease (as opposed to the related, but distinct, irritable bowel syndrome).

**INVENTIVE STEP (IS)**

Claims 1 to 13 – see the comments under novelty above.